

### **REMARKS**

Claims 138 and 173-177 have been amended. Support for the claim amendments may be found throughout the specification, for example at p. 117-121. New claims 180-181 have been added. No new matter has been added. Support for the new claims may be found, for example, throughout the specification and in the claims as filed. Applicants respectfully request the consideration of the species FveR27A once the search for the elected species Der p 2 and FveT29A is complete.

Claims 178-179 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of those claims in a continuing or divisional application.

Claims 138, 173-176 and 180-181 are pending.

### **CLAIM REJECTIONS**

#### ***Rejection of claims under 35 U.S.C. § 112, first paragraph***

##### ***Enablement***

The Examiner has rejected claims 138 and 173-179 under 35 U.S.C. § 112, first paragraph, for lack of enablement.” See Office Action at p. 3. Claims 173-177 depend from independent claim 138. Not in acquiescence to the rejection but in an effort to expedite prosecution, claims 178-179 have been cancelled thus rendering this rejection moot with respect to those claims.

The Examiner states that “the specification, while being enabling for: a method for producing the fusion proteins of SEQ ID NO: 44 and 46 using nucleic acids, vectors and host cells, does not provide reasonable enablement for: **a method for producing a polypeptide** capable of stimulating an immune response against a molecule ....” (original emphasis). *Id.* The Examiner further states that “[i]t is the Examiner’s position that the specification discloses in the Appendix on p. 165 the fusion proteins of SEQ ID NO: 44 and 46 and in a method for their production in Example 13 on pages 117-121 and Figure 16.” See Office Action at p. 4. The Examiner additionally alleges that “the claims are lacking steps that are required to produce the recited proteins.” See Office Action at p. 5. The Examiner has proposed amending “all the claims to recite the necessary elements for expression of the fusion proteins using nucleic acids, which is the only method disclosed in the specification for generating the fusion proteins.” *Id.*

In addition, the Examiner further contends that the phrase “‘having a sequence shown’ is open language that encompasses polypeptides that may comprise subsequences of the recited

sequences and may further comprise any number of additional amino acids added onto the N- and/or C-terminus of the disclosed peptide portion.” See Office Action at p. 4-5. The Examiner has proposed amending “the claims to recite, for example in claim 1, ‘comprises the FveR27A polypeptide of SEQ ID NO: 6.’” See Office Action at p. 5. Additionally, the Examiner has proposed amending the claims to recite “wherein” instead of “in which” in claims 173-179. *Id.*

Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended independent claim 138 to relate to a method for producing a polypeptide capable of stimulating an immune response against a molecule, the polypeptide including a fusion protein, the method including providing a host cell comprising an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein including a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) fused to a Fve polypeptide, (b) expressing the encoded fusion protein and (c) recovering the fusion protein. Accordingly, amended claim 138 now recites the necessary elements for expression of fusion proteins using nucleic acids. Applicants have also amended claim 138 and deleted reference to the phrase “having a sequence shown as.” Applicants have further amended claims 173-177 to replace the phrase “in which” with “wherein.”

It is clear from the above that the specification describes the invention in sufficient detail to enable a person skilled in the art to make the invention. Applicants therefore submit that claim 138 and dependent claims are sufficiently enabled by the specification as filed. Applicants respectfully request reconsideration and the withdrawal of this rejection.

### ***Written Description***

The Examiner has rejected claims 138 and 173-179 under 35 U.S.C. § 112, first paragraph, “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” See Office Action at p.5. Claims 173-177 depend from independent claim 138. Not in acquiescence to the rejection but in an effort to expedite prosecution, claims 178-179 have been cancelled thus rendering this rejection moot with respect to those claims.

The Examiner states that “Applicant is in possession of: a method for producing the fusion proteins of SEQ ID NO: 44 and 4 using nucleic acids, vectors and host cells.” See Office Action at p. 6. Further, “[i]t is the Examiner’s position that Applicant has disclosed only a

method for producing the fusion proteins of SEQ ID NO: 44 and 46 using nucleic acids, vectors and host cells; therefore the skilled artisan cannot envision all the contemplated method possibilities recited in the instant claims.” See Office Action at p. 7. The Examiner further contends that the phrase “‘having a sequence shown’ is open language that encompasses polypeptides that may comprise subsequences of the recited sequences and may further comprise any number of additional amino acids added onto the N- and/or C-terminus of the disclosed peptide portion.” See Office Action at p. 7. The Examiner has proposed amending “the claims to recite, for example in claim 1, ‘comprises the FveR27A polypeptide of SEQ ID NO: 6.’” *Id.*

Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended independent claim 138 to relate to a method for producing a polypeptide capable of stimulating an immune response against a molecule, the polypeptide including a fusion protein, the method including providing a host cell comprising an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein including a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) fused to a Fve polypeptide, (b) expressing the encoded fusion protein and (c) recovering the fusion protein. Accordingly, amended claim 138 now recites the necessary elements for expression of fusion proteins using nucleic acids. Applicants have also amended claim 138 and deleted reference to the phrase “having a sequence shown as.”

Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claim 138 and dependent claims thereof.

#### ***Patentability of New Claims 180-181***

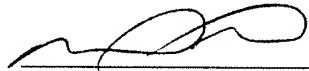
New claims 180-181 have been added and are dependent on claim 138. For at least the reasons presented above, new claims 180-181 should be found allowable.

**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. Should any further fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 9-20-10  
**Customer Number: 27890**  
STEPTOE & JOHNSON LLP  
1330 Connecticut Ave., NW  
Washington, DC 20036  
Tel: 202-429-3000  
Fax: 202-429-3902

  
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Harold H. Fox  
Reg. No. 41,498